



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION-NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,575	04/14/2000	FRANCIS JAMES ROURKE	7042-R	9622

27741 7590 12/19/2001

THE PROCTER & GAMBLE COMPANY  
PATENT DIVISION  
SHARON WOODS TECHNICAL CENTER- BOX C18  
11450 GROOMS ROAD  
CINCINNATI, OH 45242

EXAMINER

WEBB, JAMISUE A

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/529,575

Applicant(s)

ROURKE ET AL.

Examiner

Jamiesue A. Webb

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-33 and 35-40 is/are rejected.
- 7) ☒ Claim(s) 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 21-33, and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) in view of Kasahara et al. (JP 04-182,423).
3. Roe teaches a diaper containing a topsheet coated with a semisolid lotion and immobilizing agent. The lotion may be applied to the topsheet non-uniformly where portions of the surface do not have any lotion on it.

Roe however fails to provide the lotion containing a protease inhibitor. Kasahara et al. teaches protease inhibitors in the form of a lotion or emulsion where the inhibitors include trypsin inhibitor, aprotinin, soybean trypsin inhibitor, leupeptin, p-aminobenzamidine, and derivatives of guanidinobenzoic acid which may be used alone or in combination. (page 5, line 27-29 and page 6, lines 3-5). The examiner considers IC<sub>50</sub> to be an inherent property in the protease inhibitor itself. Due to the fact that Kasahara discloses many claimed protease inhibitor, then the examiner considers Kasahara to disclose all the claimed IC values.

It would have been obvious to one skilled in the art at the time the invention was made to use the protease inhibitor composition of Kasahara on the topsheet of Roe, to reduce skin irritation and prevent diaper rash. (see Kasahara page 5).

Art Unit: 3761

*Allowable Subject Matter*

4. Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Response to Arguments*

5. Applicant's arguments filed 10/18/01 have been fully considered but they are not persuasive.

6. Applicant has argued that  $IC_{50}$  is not an inherent property of material, cause it is a measure of concentration. The applicant's definition of  $IC_{50}$  in the specification is an inhibitory concentration of a substance at a specific point in a breakdown process. It is the examiner's position that the rate at which a protease inhibitor breaks down a substrate under identical test conditions cannot be changed. The inhibitory concentration of a substance cannot be changed within the substance, therefore inhibitory concentration is not a variable that can be changed, and therefore is an inherent property of the protease inhibitor. For example: the applicant discloses the soybean trypsin inhibitor having the claimed  $IC_{50}$  values, Kasahara discloses using a soybean trypsin inhibitor, it is the examiner's position that if the soybean trypsin inhibitor of Kasahara was put to the same test that to measure  $IC_{50}$  as the instant application, then it would have the same  $IC_{50}$  value. Soybean trypsin inhibitor will always have the same  $IC_{50}$  value if the same exact test was run, concentration is a test result, it is not a variable that can be changed, therefore the examiner considers  $IC_{50}$  to be an inherent property of the inhibitor itself.

Art Unit: 3761

***Conclusion***


7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jamisue A. Webb whose telephone number is (703) 308-8579. The examiner can normally be reached on M-F (8:30 - 5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John G. Weiss can be reached on (703) 308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jaw   
December 17, 2001.

  
John G. Weiss  
Supervisory Patent Examiner  
Group 3700